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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,439	11/26/2003	Harry S. Winchell	013996-001000US	6219
20350 7590 08/23/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 08/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/723,439

**Applicant(s)**

WINCHELL, HARRY S.

**Examiner**

Raymond J. Henley III

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14, 18, 21-26 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 14, 18, 21-26 and 33-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 2-12, 14, 18, 21-26 AND 33-50 ARE PRESENTED FOR EXAMINATION**

Applicant's amendment filed June 5, 2007 has been received and entered into the application. Accordingly, claims 1, 13, 15-17, 19, 20 and 27-32 have been canceled and claims 2, 14, 18, 21-24 and 33-35 have been amended.

In light of the above amendments, the rejection of the claims under 35 U.S.C. § 102(b), as set forth in the previous Office action dated April 4, 2007, is no longer adhered to and is hereby *withdrawn*. In particular, while the Examiner deems that Winchell et al. (U.S. Patent No. 5,874,573), already of record, clearly would have suggested the presently claimed compositions and methods, it is not seen that the disclosure of Winchell et al. is such that the presently claimed compositions and methods would have been "at once envisaged" therefrom, (see MPEP § 2131.02), and thus anticipated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejection - 35 USC § 103***

Claims 2-12, 14, 18, 21-26 and 33-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winchell et al., (U.S. Patent No. 5,874,573) in view of Weglicki, (U.S. Patent No. 5,854,287), each of record, for the reasons of record as set forth in the previous Office action at pages 4-5 as applied to claims 1-5, which reasons are here incorporated by reference.

Applicant's remarks at pages 12-14 of the amendment, as well as the data presented in Example 7 of the present specification, i.e., pages 89-91, have been given careful consideration, but fail to persuade the Examiner of non-obviousness.

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Regarding the primary reference, it is believed that the reference clearly provides for the elements of the presently claimed compounds such that they would have been clearly obvious to one of ordinary skill in the art. Once in the composition, the calcium chloride of the reference clearly would have formed the calcium salt which is not seen to be patentably distinct from the presently claimed "complexes". Also, the primary reference exemplifies magnesium complexes at col. 68 which would have provided the necessary suggestion to one of ordinary skill in the art to form and use magnesium complexes of those compounds having the phosphoryl moiety as presently claimed. Compounds having the phosphoryl moiety are even put more into focus by claims 13 and 14 of the primary reference.

Concerning the '287 reference, while Applicant may hold the opinion that knowledge of a compound's antioxidant activity, in and of itself, would have not been sufficient to base a conclusion of its expected activity, the Examiner's opinion of record is maintained because the Examiner's conclusion is nevertheless sound. No objective showing has been presented to establish that the Examiner's conclusion is based on an unsound basis.

As noted above, Example 7 of the present specification has been carefully considered, but cannot be afforded the significance urged because the claims are not seen to be commensurate in scope therewith. Especially given that the example involves a test with but a single magnesium complex and a single calcium complex for the treatment of ischemia following reperfusion of heart tissue.

The Examiner will agree that unexpected results have been shown for the two compounds tested against ischemia following reperfusion of heart tissue. The claims, however, are not as

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limited. Please see MPEP § 2144.08(II)(B) which the Examiner is relying on for guidance in determining whether evidence is commensurate in scope with claimed subject matter.

The claimed methods encompass the administration of a genus of compounds which is not seen to be reasonably represented by those tested. Compare, *for example*, the R<sup>2</sup> and R<sup>3</sup> groups in present claim 2 as compared to that of the compounds in Example 7. Also, it has not been established activity against ischemia following reperfusion of heart tissue may be reasonably extrapolated to neuroprotection activity as certain claims encompass.

Respecting the claims which define compositions of matter, the proffered data is seen to be totally insufficient in establishing non-obviousness because compositions are not defined by their use, but rather by their physical or chemical properties, i.e., not their biochemical properties. Thus, evidence directed to a biochemical property, which requires a step of administration or use, is not a defining characteristic of a composition of matter and is not seen to be relevant to establishing whether or not a particular composition of matter is obvious or not. An example of a characteristic of a composition which the Examiner would deem useful in showing the non-obviousness thereof would be the stability of the composition.

### ***Double Patenting***

Claims 2-12, 14, 18, 21-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,874,573, (Winchell et al.), already of record, for the reasons of record as set forth in the previous Office action as applied to claims 1-26, which reasons are here incorporated by reference.

Applicant's remarks at pages 14-15 of the amendment and the data in the present specification have been carefully considered, but are not deemed sufficient to overcome the

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rejection for the reasons set forth in the preceding section regarding the obviousness/non-obviousness of the claimed compositions, which reasons are here incorporated by reference. In particular, it is not seen that the experimental results are directed to a characteristic of the claimed compositions which could be used to show the non-obviousness of the composition, *per se*. Further, even if such were relevant, the showing of two particular compounds is not seen to be representative of the presently claimed genus.

The present claims are believed to remain properly rejected for the reasons set forth above and none of the claims are currently seen to be in condition for allowance.

Applicant's amendment necessitated the new ground of rejection, (i.e., different grouping of claims), presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

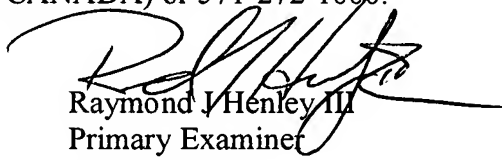
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

August 18, 2007